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24. (Amended) The method according to claim 23, wherein the pharmaceutical composition comprises at least one microorganism selected from the group consisting of *Acetobactor sp., Lactobacillus BC-Y009, Lactobacillus brevis, Lactobacillus helveticus, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus kefir, Lactobacillus keriranofaciens, Lactobacillus bifidus, Lactobacillus sake, Lactobacillus reuteri, Lactobacillus lactis, Lactobacillus delbrueckii, Lactobacillus helveticusglucos var. jugurti. and Lactococcus sp.* bacteria.

Concluded

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons which follow.

Status of the Claims

Claims 1-45 are pending in the present application. Claims 1, 2, 10, 11, 23 and 24 have been amended to define the claimed invention more distinctively, keeping in mind the examiner's concerns presented in the rejections. The amendment made herein does not constitute acquiescence to the propriety of any rejection made by the examiner, but is made merely to advance the case towards allowance.

Rejection under 35 USC §101

The examiner has rejected claims 1-2 as directed to non-statutory subject matter. Without acquiescing to the propriety of the rejection, applicants have obviated this rejection by incorporating the recitation "a biologically pure strain," into claims 1 and 2, as suggested by the examiner. In view of the amendment of claims 1 and 2, withdrawal of the rejection is respectfully requested.

Claim Rejection

I. Rejection based on 35 USC §112, first paragraph

The examiner has rejected claims 1-45 as allegedly non-enabled. Applicants respectfully traverse this rejection.

Recognizing that the microorganism is essential to the claimed invention, the examiner requires applicants to show that the microorganism is either obtainable by a repeatable method or is readily available to the public. Especially, the examiner alleges that it is not apparent if the microorganism is readily available to the public.

At the outset, applicants respectfully submit that new strains, *Lactobacillus* sp. BC-Y009 and *Acetobacter* BC-Y058 were deposited under the terms of the Budapest Treaty with the international depositary authority in Korea before the filing of the application. Applicants will submit a copy of deposit receipts together with a declaration under of 35 USC § 1.132 as to accessibility of the deposited microorganisms. The declaration will clearly confirm that a deposit of the subject microorganisms, *i.e.*, *Lactobacillus* sp. BC-Y009 and *Acetobacter* BC-Y058 have been made under conditions which would make it then available to the public as of the issue date of the patent granted, by irrevocably removing all restrictions imposed by the depositor on the availability to the public of the deposited material. Thus, applicants respectfully request that the enablement rejection with respect to claims reciting new strains be held in abeyance until the receipt of the deposit receipts and the declaration.

With respect to other microorganisms recited in the claims, applicants respectfully submit that these microorganisms have long been known and used for producing dietary fiber as clearly stated in the specification, at page 6, [0023] to [0024]. In particular, the specification refers to specific references to support the public availability of the specific microorganisms recited in the claims. See pages from 16, [0069] to 25, [0242].

Under well-established law, the PTO has the burden of contravening with "acceptable evidence" the disclosures of an application, which otherwise must be presumed correct. *In re Marzoocchi,* 439 F.2d 220 (CCPA 1967), In *re Bowen,* 492

F.2d 859, (CCPA 1974). However, in the instant case, the examiner has failed to meet this burden of providing acceptable evidence sufficient to doubt question the presumptive correctness of applicants' disclosure. Therefore, in view of the disclosure of the specification, combined with the knowledge well known in the art, applicants respectfully submit that microorganisms recited in the claim, except for two new strains, are well known and readily available to the public, which is sufficient to meet the enablement requirement. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

II. Rejection based on 35 USC § 102(a) or § 102(b)

The examiner has rejected claims 1 and 3-45 under 35 USC § 102(a) as anticipated by EP 0956867A1 (the '867 publication"). In addition, the examiner has rejected claim 2 as anticipated by the Valla reference. Applicants respectfully traverse these rejections.

At the outset, applicants note that claims 10, 11, 23 and 24 have been amended to prescribe *Lactobacillus* strains not to include *Lactobacillus* strains described in the '867 publication. The '867 publication does not teach any other microorganisms recited in the claims for the use of the treatment of diabetes. Therefore, amendments of claims 10, 11, 23 and 24 render moot the rejection of claims 10-15 and 23-28.

The examiner further asserts that because diabetes often causes weight gain and obesity, treatment of these symptoms associated with diabetes is inherent to the teachings of the reference.

Claim 2 of the '867 publication discloses a method for treating insulin resistance disease as above using a combination of the microorganisms, *i.e., Lactobacillus* acidophilus, *Lactobacillus* bifidus and *Saccharomyces* boulardii. However, there is no disclosure in the '867 publication that the combination of these three microorganisms can be used for treating obesity, controlling or reducing weight gain, controlling or reducing blood glucose level or absorption of blood lipid.

To make up for the lack of disclosure, the Examiner relies on an inherency theory. Contrary to the examiner's allegation, however, mere disclosure of treating

diabetes does not qualify as inherent disclosure of the claimed compositions or methods for treating obesity, controlling or reducing weight gain, controlling blood glucose level or absorption of blood lipid, as explained below.

According to claim 2 of the '867 publication, the method for treating insulin resistance diseases uses the microorganisms that reduce production of enterotoxic substance in the intestinal mucous, which inhibits activation of protein kinase, and, in turn, prevents from inactivation of insulin receptors. That is, the '867 publication teaches treating diabetes by controlling the production of enterotoxic substances using the specific three microorganism as described in claim 2.

In contrast, the claimed methods are based on the finding that certain microorganisms recited in the claims can convert oligosaccharides produced by digestive enzymes into non-digestible polysaccharide, thereby remarkably reducing the amount of oligosaccharides absorbed into the intestine. That is, in the claimed invention, inhibition of intestinal absorption of oligosaccharides results in treating obesity, controlling or reducing weight gain, or controlling blood glucose level or absorption of blood lipid, as well as treating diabetes. Therefore, the mechanism of action to treat diabetes is completely different between the claimed invention and the method of the '867 publication. In view of such a difference in mechanism of action, one skilled in the art would have no expectation that the three microorganisms disclosed in the '867 publication, which allegedly treat insulin resistance diseases, also exhibit effects on obesity and other biological activity as claimed in the instant application.

In relying upon the theory of inherency the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily flows** from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Applicants respectfully submit that the examiner fails to meet such burden in this case. The examiner has not provide any basis or technical reasoning how the claimed compositions or methods for treating obesity, controlling or reducing weight gain, controlling blood glucose level or absorption of blood lipid **necessarily flow** from the teachings of the '867 publication that treating diabetes by controlling the production of enterotoxic substances using the specific three microorganisms as described in claim 2.

Instead, the examiner simply alleges that diabetes often causes weight gain and obesity. However, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert,* 9 F.3d 1531, 1534 (Fed. Cir. 1993). Clearly, inherency may not be established by probabilities or possibilities. *In re Robertson,* 169 F.3d 743, 745 (Fed. Cir. 1999).

Thus, given the lack of disclosure in the '867 publication with the absence of any other objective evidence curing the missing description, a person of ordinary skill in the art would not infer from the '867 publication that the ability to treat obesity, control or reduce weight gain, or control blood glucose level or absorption of blood lipid of claims 3-9, 16-22, and 29-45 is an inherent property of the specific three microorganisms disclosed in the prior art references.

With respect to the rejection of claim 2 based on the Valla reference, applicants wish to direct the examiner's attention to the claimed invention that is a new pure strain of *Acetobacter sp.* BC-Y0058. The Valla reference describes *A. xylinum* presented in figure 8, the new strain clearly shows that the claimed strain is distinguished from *A. xylinum* described in the Valla reference.

It is axiomatic that, for a reference to be anticipatory, it must describe each and every element of the claimed invention clearly shows that the claimed strain. However, the '867 publication does not explicitly or inherently teaches the treatment of obesity, controlling or reducing weight gain, or controlling or reducing blood glucose level or absorption of blood lipid, as claimed in the instant application. Furthermore, the Valla does not disclose the new *Acetobacter* strain claimed in claim 2. Accordingly, none of the cited references discloses each and every element of the claimed invention either explicitly or inherently.

Accordingly, reconsideration and withdrawal of all of the anticipation rejections are respectfully requested.

In view of the foregoing amendments and remarks, applicants respectfully request favorable reconsideration and allowance of the pending claims. If there are any issues remaining which the examiner believes could be resolved through either a

Supplemental Response or an Examiner's Amendment, the examiner is hereby respectfully invited to contact the undersigned at the telephone number listed below. Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

Respectfully submitted,

Date 18 April 2002 By S. A. Bent

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Marked up rewritten claims:

1. (Amended) A biologically pure strain of *Lactobacillus* sp. BC-Y009 (KCTC-0774BP).

2. (Amended) A biologically pure strain of *Acetobacter* sp. BC-Y058 (KCTC-0773BP).

10. (Amended) A pharmaceutical composition comprising at least one microorganism selected from the group consisting of *Acetobacter sp., Leuconostoc sp., Bacillus sp., [Lactobacillus sp.] Lactobacillus BC-Y009, Lactobacillus brevis, Lactobacillus helveticus, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus kefir, Lactobacillus keriranofaciens, Lactobacillus bifidus, Lactobacillus sake, Lactobacillus reuteri, Lactobacillus lactis, Lactobacillus delbrueckii, Lactobacillus helveticusglucos var. jugurti., Streptococcus sp., Bifidobacterium sp., Lactococcus sp. and Pediococcus sp.* bacteria in an amount effective to prevent or treat diabetes mellitus and a pharmaceutically acceptable carrier, wherein the microorganism is capable of producing polysaccharide.

11. (Amended) The pharmaceutical composition according to claim 10, wherein said microorganism is selected from the group consisting of *Acetobactor sp., [Lactobacillus sp.] Lactobacillus BC-Y009, Lactobacillus brevis, Lactobacillus helveticus, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus kefir, Lactobacillus keriranofaciens, Lactobacillus bifidus, Lactobacillus sake, Lactobacillus reuteri, Lactobacillus lactis, Lactobacillus delbrueckii, Lactobacillus helveticusglucos var. jugurti., and Lactococcus sp.* bacteria.

23. (Amended) A method for preventing or treating diabetes mellitus, comprising administering to a subject in need thereof a [pharmaceutical] pharmaceutical composition comprising at least one microorganism selected from the group consisting of *Acetobacter sp., Leuconostoc sp., Bacillus sp., [Lactobacillus sp.] Lactobacillus BC-Y009, Lactobacillus brevis, Lactobacillus helveticus, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus kefir, Lactobacillus keriranofaciens, Lactobacillus*

bifidus, Lactobacillus sake, Lactobacillus reuteri, Lactobacillus lactis, Lactobacillus delbrueckii, Lactobacillus helveticusglucos var. jugurti., Streptococcus sp., Bifidobacterium sp., Lactococcus sp. and Pediococcus sp. bacteria in an amount effective to prevent or treat diabetes mellitus and a pharmaceutically acceptable carrier, wherein the microorganism is capable of producing polysaccharide.

24. (Amended) The method according to claim 23, wherein the pharmaceutical composition comprises at least one microorganism selected from the group consisting of *Acetobactor sp., [Lactobacillus sp.] Lactobacillus BC-Y009, Lactobacillus brevis, Lactobacillus helveticus, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus kefir, Lactobacillus keriranofaciens, Lactobacillus bifidus, Lactobacillus sake, Lactobacillus reuteri, Lactobacillus lactis, Lactobacillus delbrueckii, Lactobacillus helveticusglucos var. jugurti. and Lactococcus sp.* bacteria.